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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,110	04/05/2001	Elizabeth A. Wang	CIBT-P03-031	7778

28120 7590 03/06/2003

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EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
1654	16

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/827,110	WANG, ELIZABETH A.
	Examiner Roy Teller	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 07 January 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-68 is/are pending in the application.

4a) Of the above claim(s) 1-62 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 63-68 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> .	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

This office action is in response to Paper No: 15, received 1/7/03, in which applicant elected group II, claims 63-68, with traverse of group I, claims 1-62. Applicant also elected the species, sonic hedgehog, with traverse of the non-elected species.

The traverse of group I, claims 1-62, is not found persuasive because a search for the invention of group I would not be a complete and thorough search of the pertinent patent and non-patent technical literature. For example, the methods of group I are differently searched and classified from group II.

The traverse of the non-elected species of hedgehog polypeptides is not found persuasive because the hedgehog polypeptide sequences recited in the claims are distinct and different polypeptides on the basis of physical, chemical and biological properties.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-62 are withdrawn from consideration as directed to a non-elected invention.

Claims 63-68 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 63 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 63 recites a “bioactive fragment of a hedgehog protein”. The instant specification describes the bioactive fragment, page 9, line 24-26, “...wherein the fragment specifically agonizes or antagonizes inductive events...”. This describes what the bioactive fragment does, but it does not physically identify the fragment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 63 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63 recites a “bioactive fragment of a hedgehog protein”. The instant specification describes the bioactive fragment, page 9, line 24-26, “...wherein the fragment specifically agonizes or antagonizes inductive events...”. This describes what the bioactive fragment does, but it does not physically identify the fragment. Therefore, claim 63 is indefinite.

Claims 64-68 are included in this rejection for relying on a rejected claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 63 and 68 are rejected under 35 U.S.C. 102(a) as being anticipated by Ingham (USPN 5,844,079).

The claimed invention is drawn to a preparation comprising a sonic hedgehog polypeptide sequence in which the polypeptide is formulated for topical application to epithelial tissue.

Ingham teaches hedgehog related genes that generate and/or maintain an array of different vertebrate tissue both *in vitro* and *in vivo*, see abstract. Ingham discloses a preferred embodiment, sonic hedgehog polypeptide, column 3, lines 45-46. Ingham teaches the Shh polypeptide can comprise a fragment of at least 50, 100 or 150 amino acids in length, column 3, lines 57-58. Ingham discloses hedgehog polypeptides which include Shh sequences corresponding approximately to the natural proteolytic fragments of the hedgehog proteins, such as from about Cys-24 through Glu-188, or from about Asn-189 through Ala-475 of the human Shh protein, or analogous fragments thereto, column 3, lines 59-64. Ingham teaches a method of introducing exogenous hedgehog polypeptide at the site of treatment, which is topical, column 52, lines 42-45. Absent some evidence to the contrary, the topical treatment disclosed by Ingham would inherently be used for epithelial tissue.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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1654
2/27/03
RT

Brenda Brumback
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SUPERVISORY PATENT EXAMINER
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